IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

SIDNEY A. DIAMOND, COMMISSIONER OF PATENTS AND TRADEMARKS, *Petitioner*

v.

ANANDA M. CHAKRABARTY, *Respondent*

On Writ of Certiorari to the United States Court of Customs and Patent Appeals

BRIEF FOR THE RESPONDENT

EDWARD F. McKIE, JR.
SCHUYLER, BIRCH, McKIE & BECKETT
1000 Connecticut Avenue
Washington, D.C. 20036
202-296-5500

LEO I. MALOSSI
General Electric Company
Corporate Research and Development
P.O. Box 8
Schenectady, New York 12301
518-385-8514

Attorneys for Respondent

Of Counsel:

WILLIAM E. SCHUYLER, JR.
DALE H. HOSCHEIT

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BRIEF FOR THE RESPONDENT

QUESTION PRESENTED

Whether patent claims to a concededly novel and unobvious bacterium, made by man for treatment of oil spills, should be denied solely because the bacterium is alive.

STATEMENT

Certiorari initially was granted as to two separate and independent patent applications having in common only that claims to bacteria had been rejected by the Board of Appeals of the United States Patent and Trademark Office (hereafter "Patent Office" or "PTO") because the bacteria are alive. Both rejections were reversed by the United States Court of Customs and Patent Appeals (hereafter "the Court below" or "CCPA").

The Involved Technology

Otherwise, the two inventions are quite different. Bergy et al discovered and isolated from Arizona soil a biologically pure species of bacterium or actinomycete called "*Streptomyces vellosus,*" found to be useful in production of a previously known antibiotic called "lincomycin." Bergy's claims to the process of production of lincomycin by use of that bacterium were allowed by the Patent Examiner and never rejected because of the living nature of the bacterium. Only the claim to the bacterium itself was the subject of appeal. After certiorari was granted, but before the Government's brief was filed, that claim was cancelled, and Bergy's motion to dismiss for mootness was filed. That motion was granted January 14, 1980.

Chakrabarty worked in the field of cellular genetic engineering, sometimes called microbial genetics. His engineered bacterium, not previously existing in nature, functions to solve one of man's practical needs, getting rid of oil spills.

Oil is a mixture of several component hydrocarbon compounds. Since any given strain of known bacteria degrades only a particular component, prior biological control of oil spills involved use of a mixture of bacterial strains, each specific to a different oil component. Unfortunately, these bacterial strains do not thrive under the same conditions. As a result, when a mixture of bacterial strains is deposited on an oil spill, the bulk of the oil remains unattacked by the bacteria and is free to spread or sink, with time.

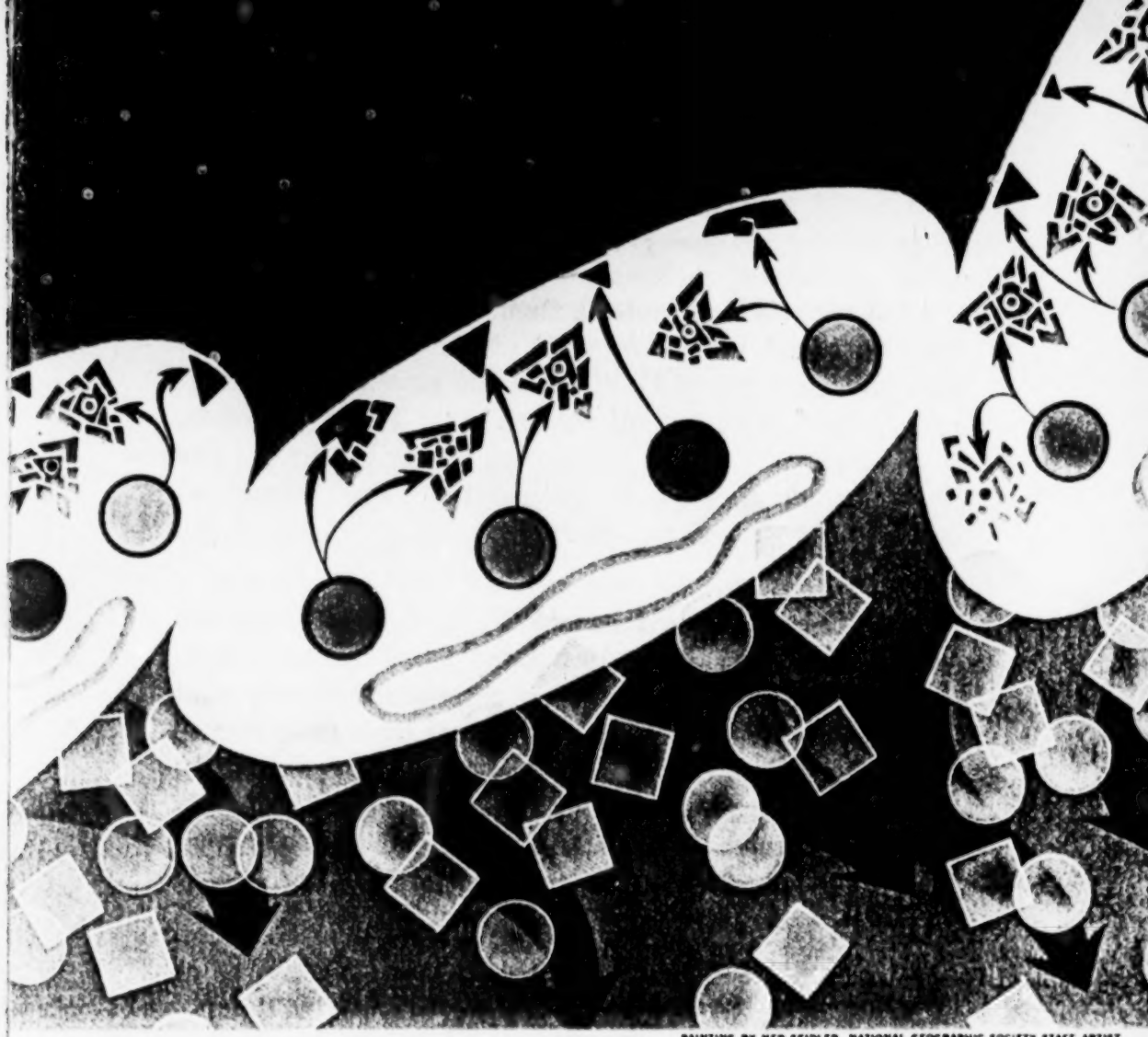
Prior to this invention Chakrabarty and Gunsalus discovered that the degradation abilities of certain bacteria are controlled by what is called a "plasmid." A plasmid is an extrachromosomal element; that is, it is a hereditary unit, physically separate from the chromosome of the cell. Chakrabarty and Gunsalus discovered plasmids in two different strains of bacteria, which were each capable of degrading a different oil component, specifically camphor and octane. However, their attempts stably to combine the respective plasmids in a single microorganism were unsuccessful.

In the work represented by the patent application involved herein, Chakrabarty discovered that plasmids capable of degrading the same two oil components, and plasmids capable of degrading two additional components, could be transmitted to and maintained stably in a single bacterium. His discovery is explained and illustrated in the following excerpt from the *National Geographic* article on "The New Biology", September 1976, Volume 150, No. 3, page 355, at 374-375 (reprinted by permission).

Breeding a superbug to attack oil spills

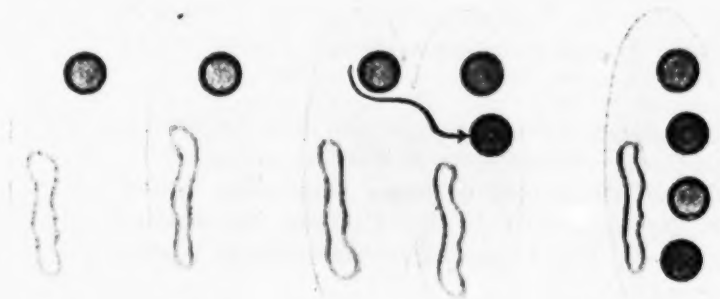
From cloudy to clear, the two vials held by Dr. Ananda M. Chakrabarty (above) of General Electric's research center demonstrate genetically engineered bacteria's gluttonous appetite for oil. By combining four strains of oil-eating bacteria, Dr. Chakrabarty has created a corps of ultrasmall scavengers (below) that one day may devour oil spills.

Natural bacteria aid in digestion and break down human wastes; perhaps a whole host of altered strains could help clean up our messy planet.



PAINTING BY NED SEIDLER, NATIONAL GEOGRAPHIC SOCIETY STAFF ARTIST

Feasting on oily waters, the superstrain *Pseudomonas* demonstrates its talents in the diagram above. Each of the four strains digests particular hydrocarbons of crude oil. But like a crowd jostling around a bargain counter, they function inefficiently. By taking a plasmid of one strain (below, green circle in diagram) that attacks specific hydrocarbons and then adding the plasmid of a different strain (red circle), a double-barreled strain is produced. Two more specialized plasmids are added (blue and orange circles). The completed bacteria are activated with ultraviolet radiation, so that they can reproduce with all four plasmids intact. The bacteria are now ready to feast.



In a mixture of oily water the bacteria digest their specified hydrocarbons (above, color-coded triangles in diagram)—up to two-thirds of the total oil present.

What remain are mostly the useful by-products water and carbon dioxide (circles and squares), and bacterial protein.

Chakrabarty's invention, then, is a new microorganism, made by him, composed of an identified bacterium having a plurality of plasmids providing for degradation of different oil components. These plasmids, if not naturally stable within the single bacterium (as the plasmids specific to the camphor and octane oil components were not), are made stable by fusion (App. 46 and 47).[1]

The Chakrabarty man-made bacterium not only has the capability of degrading multiple oil components, but it actually degrades the oil more effectively and rapidly than a mixture of individual, naturally-occurring bacteria. Chakrabarty's bacterium breaks down or degrades multiple components of the oil into simpler substances which serve as food for the bacterium. Ultimately, the bacterium becomes food for aquatic life. Thereby, noxious oil is effectively converted into a useful link in the food cycle of the sea.

Patent Office Consideration

In the Patent Office, claims to a floatable carrier inoculated with Chakrabarty's engineered bacterium have been allowed. One such claim (number 30) is as follows:

> "An inoculated medium for the degradation of liquid hydrocarbon substrate material floating on water, said inoculated medium comprising a carrier material able to float on water and bacteria from the genus *Pseudomonas* carried thereby, at least some of said bacteria each containing at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway and said carrier material being able to absorb said hydrocarbon material."[2]

[1] Chakrabarty's application is duplicated in the joint Appendix, cited as "App. ——", the darker brown volume, pages 40-77. The rejected and allowed claims are at pages 87-88. The lighter tan volume contains the Appendix to the Petition, hereinafter cited as "Pet. App. ——". The Appendix to Chakrabarty's brief is cited as "R. App. ——."

In essence, this claim covers a floatable material, such as straw (specifically recited in allowed claim 31), carrying the bacterium of the rejected claims. Claims to Chakrabarty's technique of making incompatible plasmids compatible were also allowed. Accordingly, in the normal course of events, a patent will issue on the involved patent application, containing at least claims to the bacterium on a floatable carrier, and claims to the method of making the bacterium (Opinion below, Pet. App. 2a). This appeal, therefore, is concerned not with whether a patent should issue, but rather with whether claims to Chakrabarty's bacterium, alone, should be allowed.

Claims to the bacterium itself, were finally rejected by the Patent Examiner as directed to "a thing occurring in nature" (Pet. App. 165a-167a). On appeal a three-man panel of the Board of Appeals of the Patent Office reversed as to this rejection, finding that the claimed bacterium in fact did not occur naturally but

[2] While this (and other) claims were allowed by the Patent Examiner and not rejected by the Board of Appeals, the PTO Solicitor suggested in briefing before the CCPA that this position might be erroneous and would be reconsidered upon remand to the Examiner following the appellate process:

> "Consideration has also been given to appellant's observation (Br-22) that it 'is strange indeed that claims for the bacterium on a carrier are allowable, while claims to the organism are not'. In light of the decision of the Board in *In re Bergy*, fn. 1 *supra*, there may be an anomaly, which can be rectified on return of this case to the Office." Commissioner's Brief in Patent Appeal No. 77-535.

rather was manufactured by Chakrabarty. (Pet. App. 159a, 163a). Nevertheless, the panel generated a new ground of rejection not made by the Examiner nor supported by authority. The new ground was based on the living nature of the claimed bacterium. (Pet. App. 159a-164a) [3].

Initial CCPA Consideration

The Court of Customs and Patent Appeals reversed, holding that claims to a bacterium are not excluded from patenting because of its living nature. *Application of Chakrabarty,* 571 F.2d 40 (CCPA 1978) (Pet. App. 142a-148a). That court's earlier holding in *Application of Bergy,* 563 F.2d 1031 (1977) (Pet. App. 106a-121a) was stated to be controlling.[4]

CCPA Reconsideration

This Court granted certiorari in *Bergy,* vacated the ruling of the CCPA therein, and remanded for further consideration in light of *Parker* v. *Flook,* 437 U.S.

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[3] The Board's opinion characterizes the Examiner as having rejected the claims because the bacteria are "alive". As the CCPA pointed out, this just is not true (Pet. App. 35a). The Court's reference to the "Answer" is to the "Examiner's Answer" to Chakrabarty's brief on appeal. That Answer responded to allegations in the brief that Chakrabarty's living bacteria contrasted with the living bacteria found unpatentable by this Court in *Funk Bros.* v. *Kalo Co.*, 333 U.S. 127 (1948). The Answer did not reject because Chakrabarty's bacteria are alive.

[4] Chakrabarty's application was decided by the Board before Bergy's and the rationale of the Board's majority opinion in Bergy (a different panel decided Bergy) was essentially copied from the Chakrabarty Board decision. However, the Bergy appeal to the CCPA was heard and decided before Chakrabarty, because of delay attending Chakrabarty's petition for reconsideration by the Board of Appeals.

584 (1978). Though a petition for certiorari was filed by the Government in *Chakrabarty,* it was not ruled upon by this Court. Rather, the petition was dismissed by stipulation, after the CCPA vacated its *Chakrabarty* ruling, for reconsideration of this case together with *Bergy.*

After briefing and argument of the significance of *Flook,* the CCPA affirmed its earlier judgments both in *Bergy* and *Chakrabarty* (Pet. App. 1a-70a), holding that the living nature of the claimed bacteria does not disqualify them from patent protection under 35 U.S.C. 101. More particularly, each bacterium was held to be either a "manufacture" or a "composition of matter" under that statute.

One result of the CCPA reconsideration was the change of a dissenting vote (Pet. App. 152a) on initial decision, to concurrence on reconsideration. Judge Baldwin, after careful consideration of this Court's opinion in Flook, and precedents therein cited, wrote a concurring opinion based on those precedents (Pet. App. 71a-94a).

Judge Miller dissented on the basis that the PTO had no authority to grant patents on living subject matter other than plants. His thesis was that passage of the Plant Patent Act by Congress in 1930 showed that previous Congresses, in establishing the classes of patentable subject matter, had not intended to allow patents for any living things.

The majority opinion below thoroughly considered *Parker* v. *Flook,* and its relation to this case, including the caution expressed as to areas of patentability "wholly unforeseen by Congress" 437 U.S. at 596 (Pet.

App. 20a-26a, 40a-49a). These and other considerations will be developed in the Argument section of this brief.

Petition for certiorari was applied for jointly in both *Bergy* and *Chakrabarty* and was granted on October 29, 1979. Upon cancellation of the Bergy claim to the bacterium,[5] this Court granted the Bergy motion to dismiss for mootness, also vacating the decision below as to *Bergy*, on January 14, 1980.

SUMMARY OF ARGUMENT

Keystone of the Government's position is the allegation that patenting Chakrabarty's man-made bacterium would amount to extension of the patent laws into new areas. Apart from "occasional, aberrant decisions by individual Patent Office Examiners", the Patent Office, specifically the Commissioner and the Board of Appeals, are said to have consistently interpreted the relevant statute to foreclose this type of patent.

These unsupported contentions are demonstrably false.

Patents considered by this and other courts have been issued on living things, including bacteria. In fact, so many have issued that official Patent Office specific subclasses have been established for collection of these patents. Search of these subclasses and other sources, have located many, many patents to living

[5] Contrary to the Solicitor General's response to the Bergy motion, it is understood that the Bergy application was not abandoned. Claims to the method of use of the Bergy bacterium remain allowed and the application presumably will be granted.

things. Included are ones in which the Board of Appeals has reversed an Examiner's rejection, thereby causing issuance of the patents. Indeed, a Commissioner of Patents has informed Congress that "cultures", which are living microorganisms, are patentable.

Following this consistent policy, the Examiner below allowed claims to Chakrabarty's bacteria, when innoculated onto a floatable carrier, specifically, straw. Here there is no extension of patent protection, but rather a belated attempt by the Government to reverse a long-established policy.

Chakrabarty's invention was not made by use of "recombinant DNA" techniques; misleading arguments concerning those techniques have no direct relevancy here.

The statutory history of the Plant Patent Act and the Plant Variety Protection Act are not significant evidence of the intent of the much earlier Congresses which established the statutory classes of invention. This Court has cautioned against such weak indications. Much more likely than the unexpressed purpose for which the Government contends, is that plants were not patentable because they are products of nature, a long-recognized rejection. Chakrabarty's invention, however, is admittedly not a product of nature. It is within the statutory classes of invention, as the Board of Appeals expressly below, and the Government impliedly here, recognize.

The living nature of Chakrabarty's invention should not foreclose patent protection for it. Rather, the incentive of the patent system should remain available for useful inventions, whether living or dead.

ARGUMENT

I. THE GOVERNMENT SEEKS BY THIS CASE TO REVERSE A LONG-STANDING POLICY OF GRANTING PATENTS ON LIVING THINGS

The keystone of the Government's position is that the issuance of claims to Chakrabarty's bacterium would represent an extension of patent protection into an area previously not considered patentable (Br. 9, 10, 12-16, 37-40).[6] Without any supporting evidence, it is alleged that the policy of the Patent Office always has been to refuse patents on living things (Br. 10, 39-40). This allegation is demonstrably false.

Previous Patent Office policy has been to grant patents on living things, and specifically on bacteria. That policy is demonstrated (A) by issuance of patents considered by this and other courts, (B) by official classifications of issued patents, (C) by the absence of policy statements to the contrary, and (D) by the many issued patents found in a limited search of Patent Office records.

A. Court-Considered Patents To Living Things

This Court considered a patent to a mixture of living bacteria in *Funk Bros. Co.* v. *Kalo Co.*, 333 U.S. 127 (1948).[7] Bond Patent No. 2,200,532, issued May 14, 1940 contained claims to bacteria useful in cultivation

[6] As the CCPA points out, a patent will issue on the technology of the Chakrabarty invention, whichever way this Court decides the issue before the Court (Pet. App. 2a).

[7] This case is ignored by the Government's brief, even though it was both cited and quoted in *Parker* v. *Flook*, 437 U.S. 584, 591 (1978), the decision this Court directed the CCPA to consider in connection with *Bergy* (438 U.S. 907).

of leguminous plants. No one in either the Patent Office or in the courts ever contended that the living nature of Bond's bacteria made them unpatentable.

Bond was interested in producing a mixture of different bacteria species which would respectively infect the roots of different types of leguminous plants. These different species assisted those types of plants to take nitrogen from the air and convert it into organic nitrogenous compounds, necessary to the plants' growth. Because no one species was effective for all types of leguminous plants, a mixture was necessary. However, it had previously been thought that the various species were mutually inhibitory, so as to reduce each other's efficiency. Bond found that this was not true as to some strains of these species. He claimed mutually non-inhibitive strains of the different bacterial species.

This Court held that Bond's discovery was of a natural phenomenon:

> "Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable." 333 U.S. at 131.[8]

[8] In contrast with Bond's mixture of different bacteria, Chakrabarty's invention is a single bacterium provided with additional characteristics, so that it can degrade a plurality of components of oil. The bacterium therefore performs differently to accomplish a new and better result. Compare with the reverse statements as to Bond's bacterial mixture at 333 U.S. 131:

> "Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no

Beyond that discovery, it was held that Bond had done no more than mix the bacteria together. That "simple step" was found not to be the "product of invention". 333 U.S. at 132. In modern parlance (since the 1952 enactment of the present Patent Code), what Bond did would have been obvious to the man of ordinary skill in the art (35 U.S.C. 103). (This interpretation is the same one reached by the Board of Appeals below, Pet. App. 159a, 162a-163a, and by the Government in its initial brief to the CCPA, red cover, page 19.)

To repeat, this Court applied the same criteria of patentability to Bond's bacteria as it applies to inanimate inventions. Neither here nor in the courts below was patentability questioned because the bacteria was alive. Of course, the Patent Office had not held the claims unpatentable on that basis. It had granted the patent on living subject matter, which, like Chakrabarty's invention, are bacteria.

This Court considered another patent granted by the Patent Office on living subject matter, in *American Fruit Growers* v. *Brogdex Co.*, 283 U.S. 1 (1931). Involved was Brogden et al. Patent No. 1,529,461 issued March 10, 1925. The claims defined fresh fruit whose skin carried a thin borax coating to resist blue mold decay of the fruit. Neither in the Patent Office nor in the courts was it contended that the living nature of the fruit made the claims unpatentable. This Court reversed a validity holding of the product claims on the basis that the fruit was not a "manufacture" within

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change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning."

the meaning of Section 31 of Title 35 (Rev. Stat. 4886). The borax addition was held not to provide a new or distinctive form, quality or property to the raw fruit. Nor was there any change in the name, appearance or general character of the fruit.

> "It remains a fresh orange fit only for the same beneficial uses as theretofore." 283 U.S. at 12.

In contrast, Chakrabarty's bacterium is wholly different from its natural ancestor. It is capable of degrading not just one, but a plurality of different components of spilled oil. It has added plasmids not characteristic of the "raw" product. The *American Fruit* tests qualify Chakrabarty's bacterium as a manufacture.

The Patent Office has also granted patents for mushroom spawn, which, of course, are alive. One such patent, Sinden No. 1,869,517, granted August 2, 1932, was held valid and infringed in *Pennsylvania Research Corp.* v. *Lescarboura Spawn Co.*, 29 F. Supp. 340 (E.D. Pa. 1939). No suggestion that the living nature of the claimed subject matter made it unpatentable appears in the opinion.

Living subject matter was also involved in *Guaranty Trust Co. of New York* v. *Union Solvents Corp.*, 54 F.2d 400 (D. Del. 1931), *aff'd* on lower court opinion at 61 F.2d 1041 (3d Cir. 1932), *cert. denied* 288 U.S. 614 (1933). Weizmann, the inventor of Patent No. 1,315,585, issued September 9, 1919, had found that certain bacteria "found in soil and cereals" (page 1, lines 46-47), and therefore old in nature, could be used to make acetone and methyl alcohol. Only process claims to the method of making those materials, using the "found" bacteria, were issued. One of the defenses

rejected by the District Court in finding the patent valid and infringed, was that the life process of a living organism is unpatentable.[9]

B. Official Patent Office Classifications of Issued Patents On Living Subject Matter

The Patent Office has granted so many patents on live subject matter that it has established official subclasses of such patents, based on the inventions claimed therein. These subclasses facilitate novelty investigations both by Patent Examiners and the general public. For instance, Class 424 is entitled "Drug, Bio-Affecting and Body Treating Compositions". The official "Classification Definitions" for Class 424 say:

> "Class 424 provides for compositions containing microorganisms, either alive, dead or attenuated;" (page 424-6).

Class 424 contains a Subclass 93 entitled:

"Whole Live Microorganism or Virus Containing".

The January 1979 subclass list of Class 195 "Chemistry, Fermentation" contained a Subclass 53 entitled:

> "Ferment-Containing Products . . ., Living fungi-containing".

Class 195 was replaced in July 1979 by Class 435 "Chemistry: Molecular Biology and Microbiology". Subclass 235 of that class is for "Viruses", etc., and

[9] To the same effect are *Cameron Septic Tank Co.* v. *Village of Saratoga Springs*, 159 Fed. 453, 458 (2d Cir. 1908), *cert. denied* 209 U.S. 548 (1908), cited with approval by this Court in *Funk Bros. Co.* v. *Kalo Co.*, *supra*, 333 U.S. at 130; *City of Milwaukee* v. *Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934), *cert. denied* 293 U.S. 576 (1934); *Ex parte Prescott*, 19 U.S.P.Q. 178 (P.O. Bd. App. 1932).

Subclass 243 for "Microorganism Per Se", etc. The official Class Definitions contain a section titled "II. Classification Lines With Other Classes". Under that heading appears the following:

> "Class 424, Drug, Bio-Affecting and Body Treating Compositions, for a process of treating the living body with a microorganism or enzyme and the compositions therefor which may contain a live microorganism, co-enzyme, or enzyme . . . See especially . . . Subclass 93 for a composition including whole live microorganism or virus . . . Class 435 provides for . . . the virus or microorganism per se . . ." (page 435-1 - 4).

Certainly, these subclasses would not have been established and defined by Patent Office officials unless patents had been granted to be placed in the subclasses.

C. Official Expressions Of Patent Office Policy Identify Characteristics Other Than Life As Making Subjects Non-Statutory

The policy of the Patent Office is stated in the Rules and, since 1949, detailed in the official "Manual of Patent Examining Procedure". Both are silent as to living things, though the Manual lists the types of subject matter not considered by the Office to be within the ambit of 35 U.S.C. 101, as "Printed Matter", "Naturally Occurring Article", "Method of Doing Business" and "Scientific Principle".[10] As noted in the Statement above (page 7), the Examiner rejected the

[10] A copy of the indicated portion of the official Manual is attached in Respondent's Appendix (R. App. 1a). Hereafter in this Brief, reference to Respondent's Appendix will indicate that the material in question is at the indicated location in the Appendix.

claims here in issue as directed to a naturally occurring article, an officially recognized disqualification. Of course they are not, because the plural plasmid, plural component eating bacterium did not occur in nature, until Chakrabarty made it. The Board (Pet. App. 163a) agreed that was so. The Government does not contend otherwise.

If there had been a Patent Office policy to reject patents on living things, it would have been expressed with these other non-statutory exclusions in the Manual. It is not, nor has it ever been.

D. Searches Through These And Other Subclasses And Other Sources Have Identified Many Patents Claiming Live Subject Matter

Subclass 93 of Class 424, the "live microorganism" subclass, contains 138 patents. The first patent in the subclass, No. 952,418, was issued in 1910. It claims a living microorganism, such as lactic acid bacillus, mixed with cocoa or chocolate. The claimed utility is as a food product.

In addition to Subclass 93, we have conducted searches through other subclasses of Class 424 and through various subclasses of Class 435. Through those and other sources we have collected over 60 issued patents (R. App. 16a-18a) claiming living subject matter, mostly bacteria. These searches were made in response to the Government's contrived contention that Patent Office policy always has been not to grant patents on living things and that the few prior patents referred to in the CCPA opinion (Pet. App. 66a, 67a) are mere aberrations of some of the 1000 plus Examiners of the Patent Office, but not of the Commissioner or the Board of Appeals (Br. 38-40). Here are no mere

aberrations. Here is evidence of a consistent Patent Office policy, a policy the Government now seeks to change by this case.

Among these 60+ patents, we noted particularly that the Board of Appeals (including Mr. Magil, later a member of the *Chakrabarty* Board) reversed an Examiner's rejection of claims to living bacteria. This rejection was that the claims were for a discovery of nature, citing *Funk Bros. Co.* v. *Kalo Co., supra,* 333 U.S. 127 (1948). The Board reversed this rejection, stating agreement with the applicant's characterization of his invention as the "nonobvious manipulation, utilization or application of known things to produce a utilitarian tangible composition of matter." The Board's opinion, published with the entire prosecution history of that patent (Farr Patent No. 3,420,742, January 7, 1969, R. App. 2a), also contained the following:

> "We note that the patents cited in the Examiner's action, Paper No. 4, contain claims to cultures of bacteria. Attention is also directed to *In re* Davis et al., 49 CCPA 1196; 305 F.2d 501 . . . which presented claims to vaccines containing both live and dead antigens of either viral or bacterial origin."[11] (R. App. 6a)

The patents referred to by the Board are Reichel et al. 1,957,555, May 8, 1934; and Nordsiek 2,121,442, June 21, 1938. The former claims a stabilized bacterium; the latter, a mixture of two bacteria.

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[11] The Patent Office reconsidered this Farr patent through Farr's application for reissue. Claims to the bacteria were reissued in Reissue Patent No. 28,488 on July 22, 1975.

Contrary to the Government's unsupported allegation, the Board, like the Examiners whose rejections they review, has interpreted the statutes to allow patents on living microorganisms.

A later patent Morimoto et al. No. 3,642,982, patented February 15, 1972 (R. App. 9a), not only claims "living bacteria", the title was change by Examiner's amendment to be:

> "The Utilization of Living Bacteria as Insecticides."

The claims of the last patent recite a carrier, specifically an insecticidal carrier, e.g.:

> "1. An insecticidal composition containing living bacteria consisting essentially of an inert insecticidal carrier and *Serratia piscatorum* ATCC No. 17999 or *Streptococcus faecalis* ATCC Nos. 15335, 14336 and 19000, the living bacterium being present in an amount of 0.05 to 5 weight percent."

Claim 1 of Morimoto claims "living bacteria", even though the living bacteria are claimed in combination with a carrier. In similar fashion, claims allowed to Chakrabarty claim his bacterium with a carrier. See above, pages 6-7.

Macpherson et al. Patent No. 3,228,840, January 11, 1966, similarly claims a hamster cell line in a nutrient culture medium.

Green Patent No. 4,003,789, January 18, 1977, claims a mouse cell line in a suitable growth medium. The claims were rejected as nonstatutory. In repeated responses, the applicant pointed out that the claimed product did not occur in nature but rather was significantly modified. Finally, in a brief to the Board of Appeals, the applicant also said:

> ". . . living microorganisms have been held to be patentable subject matter. For example, live viruses in the form of vaccines have been held to be proper subjects for patents as long as they meet the other requirements for patentability. *Ex parte Plotkin*, 174 U.S.P.Q. 39 (P.O. Bd. App., 1971); *In re Bankowski*, 138 U.S.P.Q. 75 (C.C. P.A. 1963); and, *Dick et al.* v. *Lederle Antitoxin Laboratories*, 6 U.S.P.Q. 40 (S.D.N.Y., 1930)."

The Examiner thereupon withdrew his rejection and the claims were allowed.

In Bordt et al. Patent No. 4,070,453, January 24, 1978, claims to a porcine cell strain were presented. When amended to recite a "suitable culture therefor", they were allowed. (R. App. 11a)

Goldberg Patent No. 4,166,112, August 28, 1979 (R. App. 13a), solicited by the Government from the Government, claims specific bacteria and "a carrier."

These patents clearly claim living things; the additional recitation of such inanimate things as a carrier does not change that fact. Moreover, the Patent Office also has granted patents on living things not claimed with inanimate things.

Treichler et al. Patent No. 3,923,601, December 2, 1975, claims a colony of a fungus mutant, a living thing not combined with anything else.

Smith Patents Nos. 3,356,574, December 5, 1967, and 3,364,117, January 16, 1968, each claims a freeze-dried culture of a different specific bacterium.

Smith et al. Patent No. 3,709,782, January 9, 1973, claims mammal cells, a feline cell line useful in production of vaccines. While the application was never rejected as directed to living subject matter, claims to the cell line were rejected as products of nature. In response, the applicant not only rebutted that rejection but expressly called attention to the living nature of his compositions:

> "The fact that some compositions have certain characteristics of living matter is not *per se* an obstacle for their inclusion as statutory subject matter. For example, vaccines, serums, yeast compositions, viral suspensions, and the like, have all been the subject of U.S. patents, and Patent Office classification supports this view. Thus, Class 424/93 covers 'Whole Live Microorganisms or Virus Containing Non-Immunologic Materials . . .' "

After limitation of the cell line claim to recite it as the product of a claimed process, it was then allowed.

The Government's brief (Br. 38-40) criticizes the CCPA for relying on patents cited as covering living matter in an article written by three Patent Office Examiners, 10 IDEA 87 (1966). This article takes the position that patent protection is available for microorganisms and suggests claiming them as compositions of matter. The alleged "consistent"policy of the Patent Office evidently was not communicated to the authors, despite early publication of their views, and their evident responsibility for subject matter of this kind. To the contrary, the article quotes a then Commissioner of Patents as having told the Congress that patents are granted on "cultures," 10 IDEA at 95. The cited Senate Report No. 932, 86th Cong., 1st Sess., 1959, quotes a letter from Commissioner of Patents

Watson dated March 13, 1959, to Senator O'Mahoney, then Chairman of the Senate Subcommittee on Patents. The letter states:

> "Patents are granted on cultures and pharmaceuticals; and under the plant patent statute on plants bearing edible fruits and nuts." (page 7)

Cultures are defined in *Fundamentals of Microbiology,* Frobisher et al., Ninth ed., W. B. Saunders Co., Philadelphia, 1974, page 790:

> "Any growth, population, or cultivation of microorganisms."

As to several patents referred to by the Patent Examiners in the IDEA paper, the Government states that they "claim a virus, which some scientists consider to be without life." (Br. 39, fn 46).[12] It is assumed, therefore, that Patent Office policy admittedly is that viruses can legitimately be claimed in patents. This conclusion is confirmed by the Board of Appeals decision in *Ex parte Plotkin,* 174 U.S.P.Q. 39 (1971). (Messrs. Magil and Schneider, from the *Chakrabarty* board, were members of the *Plotkin* board.) The searches referred to above have identified nearly 200 patents claiming viruses. It is well that the Patent Office does not seek to invalidate those 200+ patents, as they do the 60+ patents identified herein.

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[12] The Government's reference in footnote 47 to Mr. Federico's comment as to Pasteur's yeast patent omits to say that the authority he cited for his doubt concerning patentability was this Court's opinion in *American Fruit Growers* v. *Brogdex,* 283 U.S. 1 (1931). That decision did not criticize the living nature of the subject, but rather its natural character. Again, Chakrabarty's bacterium does not occur in nature.

This is not a case similar to that in *Parker* v. *Flook,* 437 U.S. 584, 595 (1978) in which the

> ". . . youth of the industry may explain the complete absence of precedent supporting patentability."

Here, the technology, broadly, is old. The court below quoted the Patent Office Solicitor at oral argument to that very effect (Pet. App. 68a). Moreover, there is an abundance of precedents, supporting patentability, above recited.

Expanding upon a statement made in *Parker* v. *Flook,* 437 U.S. at 596, the Government appears to contend that only technologies foreseen by Congress at the time it passes a patent law are within that law. Illustrations of technologies certainly not foreseen by Congress when it passed the 1836 Act, the 1874 Act or the 1952 Act are not hard to imagine. Did the 1874 Congress foresee airplanes, photocopying machines, computers, antibiotics? All were patented. Must the Congress re-pass 35 U.S.C. 101 every year to insure that new technologies, the very reason for the statute, are within it? *Application of Sarkar,* 588 F.2d 1330, 1333 (CCPA 1978). This Court has said:

> ". . . if Congress has made a choice of language which fairly brings a given situation within a statute, it is unimportant that the particular application may not have been contemplated by the legislatures." *Barr* v. *United States,* 324 U.S. 83, 90 (1945).

Available evidence proves that, before this case, "consistent" Patent Office policy had been to grant patents directed to living things. Here is no extension

of patentable subject matter. Here is reversal of a Patent Office policy and an attempt at restriction of patentable subject matter.

II. CHAKRABARTY'S INVENTION DOES NOT INVOLVE RECOMBINANT DNA; HAZARDS IN SUCH RESEARCH HAVE PROVEN TO BE LESS THAN EXPECTED; HEW HAS SO RECOGNIZED; CONGRESS HAS REFUSED TO REGULATE; ANY REGULATION SHOULD BE DIRECT

The Government's brief cites controversy connected with research known as "recombinant DNA" as justification for denial of Chakrabarty's claims (Br. 17-21). Those claims do not involve recombinant DNA, as the Government admits (Br. 17-18). Some explanation is necessary to put this point in perspective.

Genes determine the characteristics of microorganisms, as well as those of other types of cells. The principal substance of the genes is deoxyribonucleic acid (DNA).

> "DNA plays to two roles: (1) provides information for the reproduction, growth, and functions of the cell, and (2) preserves and directs replication of this information and transfers it to the offspring. These two roles of DNA are common to animals, plants, single-cell organisms, and many viruses. The DNA of cells is mainly found in organized structures called 'chromosomes'.
>
> "Intracellular DNA also occurs outside of the chromosomes as separately replicating molecules. Such DNA molecules include the plasmids, found in bacteria; . . ." Proposed Revised Guidelines, Recombinant DNA Research, National Institutes of Health, DHEW, July 28, 1978, 43 Fed. Reg. 33100.

Materials called "restriction enzymes" are capable of splitting DNA molecules into fragments. Certain ones of these enzymes leave the split fragments with so-called "sticky ends". Recombinant DNA involves associating together genes of different species and then recombining the split fragments by virtue of these "sticky ends". The splitting, associating and recombining all take place outside of the cells, so-called "in vitro", rather than "in vivo". Proposed Revised Guidelines, *supra,* 43 Fed. Reg. 33101. (These guidelines contain an excellent short, simplified description of the recombinant DNA process, with diagram, reproduced at R. App. 20a, 21a.)

Chakrabarty did not use the recombinant DNA method in his research. As the Proposed Guidelines state, recombinant DNA was first successfully practiced in 1973; Chakrabarty's patent application was filed in 1972. Chakrabarty's work was carried out "in vivo", since he caused the plasmids to migrate from cell to cell, without any splitting or recombining outside the cells.

The Government's seizure upon the recombinant DNA matter [13] demonstrates how far they must go to attempt to justify their policy change toward refusal of patents on living microorganisms. Whether patents are to be granted on the recombinant DNA technique

[13] The Government's speculation, with the Peoples Business Commission (Br. 18, fn. 19), that patenting leads to reduction in variety, conflicts with the finding of the House Agriculture Committee which recommended passage of the Plant Variety Protection Act, that patenting:

> ". . . will give farmers and gardeners more choice, and varieties which are better in yield or in quality . . ." 116 Cong. Rec. 40296, December 8, 1970.

or its products is quite a different issue from whether Chakrabarty's different invention is patentable. Nevertheless, a holding here that living bacteria cannot be patented would seriously impact upon recombinant DNA research. The presence here, as *amici*, of organizations involved in such research demonstrates that impact.

While the interests of *amici* are best presented by them, we must here respond briefly to the distortion of the record presented by the recombinant DNA portion of the Government's brief (Br. 18-21).

Concern for the danger of recombinant DNA research has considerably diminished in recent years. The 1976 Guidelines imposed by NIH on recombinant DNA research it sponsors (41 Fed. Reg. 27902, July 7, 1976) were considerably relaxed 2½ years later (Revised Guidelines, etc., 43 Fed. Reg. 60080, December 22, 1978). A recent publication cited in the Government's brief (Br. 20) reports that the committee which generated the Guidelines has recommended a further relaxation, to the point that 80-85% of the area impacted by the original Guidelines would be de-controlled. *Science,* Vol. 205, September 21, 1979, page 1238. On November 30, 1979, NIH published the following statement in the Federal Register:

> *"Lack of Demonstrated Hazard to Date*
>
> The Environmental Impact Assessment of July 1978 stated, 'No evidence has come to light that any of the thousands of individual recombinant DNA clones constructed over the last 5 years have yielded a product harmful to man or the environment. On the other hand, many examples of useful knowledge obtained through such techniques continue to accumulate rapidly.' The negative aspect of this statement remains unchanged as of

this date. The useful new knowledge obtained through the use of the technology has continued to accrue." 44 Fed. Reg. 69241. (emphasis in original)

Moreover, the Congress, which considered legislating controls on recombinant DNA research, has evidently given up that project. "Science and Technology" the congressionally-mandated report by the National Academy of Sciences, recently had this to say on the subject:

> "The anxiety over recombinant DNA research has abated considerably, for several reasons. Among those is the failure of five years experience to produce evidence of any illness or other harm. In addition, sober professional analyses have gradually displaced earlier unrealistic demands for absolute protection against hypothetical risks." Accordingly, the NIH guidelines are gradually being relaxed; and the Congress has determined that the guidelines are adequate for handling the problem without legislation." Science and Technology, A Five-Year Outlook, National Academy of Sciences, W. H. Freeman and Co., San Francisco 1979, page 134.

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[14] The "Peoples Business Commission", *amicus curiae*, evidently is a holdout. Having been unsuccessful in other fori, they here seek to discourage affirmance of the CCPA holding which would, they say:

> ". . . significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies. This, in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life." (page 3).

To a supporter of both private enterprise and the patent incentive for private enterprise, this sounds like an argument for affirmance.

See also letter to Secretary Califano of DHEW, by Senators Kennedy and Javits, respectively, Chairman and Ranking Minority Member of the relevant Senate subcommittee and committee, dated June 1, 1978, reproduced with the Revised Guidelines, Recombinant DNA Research (43 Fed. Reg. 60103-4) December 22, 1978:

> "In the past, Congress has been reluctant to extend statutory control over a specific field of scientific investigation unless such authority was absolutely necessary to protect the public's health and safety. In view of the scientific evidence accumulated during the past year, it is not possible to reach this conclusion in the case of recombinant DNA research."

It is axiomatic that any dangers to the public's health and safety are best prevented by regulation of the source of those dangers, not by an indirect approach that would prevent patenting the results of research.[15] Moreover, where the Congress has refused to act to control recombinant DNA research, at the urging of the Government,[16] after "four committees of the House and Senate have held nine series of hearings to consider the issues relating to recombinant DNA research" (Kennedy and Javits letter of June 1,

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[15] "The Patent and Trademark Office has nothing to do with *regulating use* of technology. The Government is adequately supplied with numerous other agencies able and eager to perform that function." *Application of Sarkar*, 588 F.2d 1330, 1333 fn 8 (CCPA 1978) (emphasis in original).

[16] Proposed Revised Guidelines, Recombinant DNA Research, Tuesday, September 27, 1977, 42 Fed. Reg. 49596.

> "A Federal Interagency Committee on Recombinant DNA Research recommended in March 1977 that legislation be passed to extend the standards of the NIH Guidelines to all recombinant DNA activities in the public and private sectors."

1978, *supra*),[17] the Government stands on weak ground in urging discouragement to the research by this Court.

Inconsistency is the very hallmark of the Government's activities in this area. On January 13, 1977, the Patent Office announced a new program to accord "special status" to patent applications involving recombinant DNA research so as to expedite their consideration, and thereby their publication. The notice emphasized the benefits of such research, saying:

> "Recombinant DNA research appears to have extraordinary potential benefit for mankind. It has been suggested, for example, that research in this field might lead to ways of controlling or treating cancer and hereditary defects. The technology also has possible applications in agriculture and industry. It has been likened in importance to the discovery of nuclear fission and fusion." 42 Fed. Reg. 2712

The special status program was later withdrawn, 42 Fed. Reg. 13147, March 9, 1977,[18] but the same Government which here seeks to discourage recombinant DNA research, encourages that research by hundreds of research contracts sponsored by NIH (500 plus, according to Senator Stevenson's remarks on the Senate floor on October 14, 1978, Cong. Rec. S 19351. A very recent publication, cited by the Government, quotes a government official that 720 projects are currently sponsored by NIII, *Chemical Week,* September 26, 1979, page 34.)

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[17] See also H. Rep. Report No. 95-1005, 95th Cong., 2d Sess., on H.R. 11192.

[18] Patent Office Official Classification Class 435, Subclass 172, is for patents claiming "Mutation or Genetic Engineering." There are 92 patents in that subclass.

As this brief is being written, the *Washington Post* of January 17, 1980 reports (page A7) researchers' success in producing interferon by a genetically-engineered bacterium. The prohibitive cost of prior methods of production of that very promising drug is expected to be brought to manageable levels, by use of the new man-made bacterium.

Recombinant DNA research and any controversies concerning it, furnish no basis for denying patents on bacteria because they are alive. Indeed, inhibition to the making and disclosure [19] of recombinant DNA inventions, by outlawing patents on living microorganisms, may adversely affect that research and its great promise for mankind.

III. THE GOVERNMENT'S MISCELLANEOUS "AUTHORITIES" DO NOT SUPPORT ITS CONTENTION THAT MICROORGANISMS HAVE ALWAYS BEEN UNPATENTABLE

While ignoring the objective evidence furnished by the patents it has issued, both those in litigation and the great majority which were not, and its own official patent subclass classification, the Government relies on admitted dicta, obviously equivocal, the title of a resolution adopted by a bar association and various other "authorities". Their weight, even if added together, does not approach that of the objective evidence to the contrary.

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[19] A graphic example of the significance of the patent to disclosure of an invention is furnished by the recent case of *Application of Sarkar*, 588 F.2d 1330, 1332, 1333 (CCPA 1978). The applicant was desirous of preserving his trade secret rights in his mathematical formula and therefore successfully requested *in camera* treatment of the formula. Since the court affirmed the Patent Office rejection, the patent will not be granted and the formula will not be published.

Guaranty Trust Co. of New York v. *Union Solvents Corp.*, 54 F.2d 400 (D. Del. 1931) *aff'd* on the lower court opinion 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933), concerned a patent on a method of producing acetone and butyl alcohol by use of a bacterium which Mr. Weizmann had found in nature. The patent was sustained, the court rejecting the contention that it was for the life process of a living organism. The court contrasted the bacterium, found in nature and therefore not novel, with the method of its use:

> "Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. Were the patent for bacteria per se, a different situation would be presented. As before stated, the patent is not for bacteria per se. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. Undoubtedly there is patentable subject matter in the invention." 54 F.2d at 410.

Since the bacterium was old in nature, it might well have been unpatentable if claimed alone, which it was not. In any event, comments on patentability of nonexistent claims clearly were dicta.

Similarly, in *Application of Mancy*, 499 F. 2d 1289 (CCPA 1974), the court, per Judge Rich, was concerned with claims to a process of producing a specific antibiotic, by use of a particular microorganism which had been found in nature. The court was not concerned with claims to the microorganism itself, but rather only with claims to the method. Nevertheless, it made the following expressly qualified statement:

> "Here appellants not only have no allowed claims to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature'." 499 F.2d at 1294.

In his opinion below, the same Judge Rich emphasized that the purpose of the quoted statement was merely a comparison between the facts of *Mancy* and those of *Application of Kuehl*, 475 F.2d 658 (CCPA 1973), in which the involved catalyst was itself claimed, as was the method of its use. No comment on patentability of living organisms was intended. Only a comment, later questioned, on novelty of the microorganism. (Pet. App. 46a-47a.)

The Government's criticism of the interpretation below of the language in *Mancy* (Br. 13, fn. 11) sounds like a return to the Examiner's "product of nature" rejection, rejected by the Board of Appeals (Pet. App. 163a). In any event, the comparison is admittedly relevant only to *Bergy*, not to this case.

The Government also contends (Br. 14, fn. 11) that "the issue of living organism patentability was raised, but not decided in *Application of Merat*, 519 F.2d 1390, 1363 (CCPA 1975)." That is not correct. The Board had said that "a thing occurring in nature" may not be patented. The CCPA did not decide that issue but sustained the rejection on other grounds.

We must again emphasize that the "product of nature" rejection, recognized by the official Manual of Patent Examining Procedure § 706.03(a) (R. App. 1a), applied by the Board in *Merat* and referred to by the court in *Mancy* is not the same as the "living thing" rejection. The Board of Appeals below recog-

nized the difference, overruling the "product of nature" rejection as to Chakrabarty (Pet. App. 163a), though applying the new unrecognized "living thing" rejection in conflict with its earlier decisions.

The American Bar Association Section of Patent, Trademark and Copyright Law did not act on the title relied on by the Government's extended footnote (Br. 14, fn. 12). It acted only on the resolution. That resolution favors "application of the principles of the Patent System to all the agricultural arts (including all plants, sexual seed breeding, micro-organisms, and animal husbandry)". 1966 *Summary of Proceedings* 74, Section of Patent, Trademark and Copyright Law, American Bar Association. Of course the Chakrabarty bacterium is not within the agricultural arts. The resolution does not apply. Moreover, that resolution and the American Patent Law Association resolution excerpted in the same footnote, respectively, were anticipation of, and reaction to, a proposal in the 1966 Report of the President's Commission on the Patent System. That Report recommended sweeping changes to the patent laws, including elimination of patent protection for plant patents. Both patent law organizations opposed that recommendation.

The ABA committee report recommending the Government-cited resolution stated the following:

> "There is no logical reason why asexually reproduced plants and microorganisms should be covered by patents as at present, while sexually reproduced ones are not covered by patents." 1966 *Committee Reports* 77, Section of Patent, Trademark and Copyright Law, American Bar Association.

Chakrabarty's bacterium is asexually reproduced. Does the Government agree with the committee whose

work it quotes, that the patent law in 1966 covered asexually reproduced microorganisms? If so, they contradict their own principal contention here.

It is noteworthy that the patent law revision bills (containing an entire proposed Title 35) recommended by the same ABA committee during the next year contain no provision for "extending" patent protection to microorganisms. 1967 *Summary of Proceedings,* Special Meeting, Washington, D. C., pages 33-62, 106-139; *Same,* Honolulu, pages 68-78, 81-101, 152-179. Perhaps the committee recognized it to be unnecessary to do so, because microorganisms are within existing law.

In any event, the same ABA Patent Section supported the holding below that existing law does not foreclose patenting living bacteria, at 1978 *Summary of Proceedings* 31 (noted below at Pet. App. 6a).

The Government's references to 1969 and 1976 ABA Patent Section actions, concern amendment of the Plant Patent law to include microorganisms, an entirely different matter than whether 35 U.S.C. 101 covers microorganisms. In the first place, there was an express authoritative holding that microorganisms were not plants, within the meaning of the then-existing plant patent laws. *In re Arzberger,* 112 F.2d 834 (CCPA 1940). In the second place, if the statute was amended to overrule *Arzberger* and qualify microorganisms as plants, the relaxation of the disclosure requirements of 35 U.S.C. 112, provided to plants by Section 162, would also be applicable to microorganisms. It is not now applicable. That the Patent Section may have desired that result is not at all relevant to

whether bacteria are patentable under Section 101, because they are alive.

The bar association activities are not support for the Government's position.

Cited text writers did not state that microorganisms are outside the present law. Mr. Dienner of course was concerned with plants and animals, not with microorganisms. Neither he nor the other writers cited by the Government (Br. 14, 15) suggested that the living nature of the things they wished patented, prevented their being patented.

The capabilities of the Congress in passing legislation for the future (Br. 16, 17) are not relevant to the coverage of existing law.

The difficulty of description of microorganisms (Br. 16, fn. 14) has been solved by the Government-approved deposit procedure. The CCPA has approved this procedure in *Application of Argoudelis,* 434 F.2d 1390 (1970) and *Feldman* v. *Aunstrup,* 517 F.2d 1351 (1975), *cert. denied* 424 U.S. 912 (1976). The Government's reference to that already-solved problem is no more support for denial of claims to the deposited bacterium than it would be to the combination of the bacterium with a carrier, or to the method of use of the bacterium. (As pointed out above, claims to these subjects have been allowed.)

But the Government's criticism of the CCPA for not explaining why its conclusion does not apply to subject matter not before the court (Br. 17, fn. 16) is the most incredible assertion of all. The hypotheticals suggested as to other living organisms are properly decided when cases or controversies involving

those subjects matter are presented. In any event, the solution to the description problem furnished by the aforesaid deposit system obviously would not apply to animals and humans. Clearly, problems in providing an enabling disclosure would be present and likely would bar patenting. As to humans, constitutional problems would seem to afflict a patent granting someone the right to exclude others from reproducing a human being. A more precise consideration is appropriately postponed until a case or controversy makes a decision necessary.

The Government's authorities do not prove its thesis.

IV. CHAKRABARTY'S BACTERIUM IS WITHIN THE STATUTORY CLASSES OF SECTION 101

Chakrabarty's man-made bacterium, a composition of a bacterium having at least two plasmids each establishing a degradative pathway for a different oil component, is within either or both of two classes of subject matter established by Congress.[20] Section 101 of Title 35, U.S.C. Code states:[21]

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement

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[20] Clearly, the bacterium relates to the "useful arts", the constitutional objective of the patent system. Constitution, Article I, Section 8, Clause 8

> "The Congress shall have Power • • • [8] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. . . ."

Any more "useful art" than cleanup of oil spills would be hard to imagine. The Government does not suggest otherwise.

[21] 66 Stat. 792.

thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

A. Manufacture

The term "manufacture" has an extremely broad connotation. In the Committee Report on the legislation which became Title 35, the following was said as to that term in Section 101:

> "A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, . . ." [22]

That language goes back to the oft-cited language of *Johnson* v. *Johnston,* 60 Fed. 618, 620 (W.D. Pa. 1894):

> "The term 'manufacture', as used in the patent law, has a very comprehensive sense, embracing whatever is made by the art or industry of man, not being a machine, a composition of matter, or a design. Curt. Pat. § 27, 1 Rob. Pat. § 183."

The following courts of appeals cases quoted *Johnson* with approval: *Binney & Smith Co.* v. *United Carbon Co.,* 125 F.2d 255 (4th Cir. 1942), reversed on other grounds, 317 U.S. 228 (1942); *Riter-Conley Mfg. Co.* v. *Aiken,* 203 Fed. 699, 701 (3d Cir. 1913), *cert. denied* 229 U.S. 617 (1913); *International Mausoleum Co.* v. *Sievert,* 213 Fed. 225 (6th Cir. 1914). To the same effect are *Park-In Theatres* v. *Rogers,* 130 F.2d 745, 747 (9th Cir. 1942) and *In re Hadden,* 20 F.2d 275 (D.C. Cir. 1927).

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[22] H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952), page 6; Senate Rep. No. 1979 (1952), U.S. Code, Cong. and Admin. News, page 2399.

Decisions of this Court are not contrary. In *American Fruit Growers* v. *Brogdex Co.,* 283 U.S. 1 (1931) citrus fruit whose skin carried a small amount of borax was held not to be a "manufacture", the Court expressly stating:

> " 'Manufacture,' as well defined by the Century Dictionary, is 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.' Also, 'anything made for use from raw or prepared materials.'
>
> "Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore." 283 U.S. at 11, 12.

A patent to a treated fur was challenged upon the authority of *American Fruit Growers,* in *Steinfur Patents Corp.* v. *Beyer,* 62 F.2d 238, 240 (2d Cir. 1932). Rejecting the challenge, the court said:

> "It can hardly be doubted that a naturally dark-colored skin which has been bleached and dyed a light color is an article of manufacture. Certainly it cannot be said of it, as of the orange, that there is no change in its 'name, appearance or general character.' In none of the three stages sought to be protected by the present patent were the dressed skins in their natural state. While it was true of the orange that impregnation of its rind with borax only protected the natural article against

> deterioration by mold and gave it no new beneficial uses, the same cannot be said of impregnation of the unbleached skin with ferrous sulphate. By such impregnation the skin attains a new quality which gives it a new beneficial use; it fits it to be used for bleaching by a method which could not without such impregnation be successfully employed. An orange has the same use whether or not impregnated with borax. A fur skin unimpregnated with ferrous sulphate cannot be used in the same way as one which has been so impegnated. The orange case does not, in our opinion, require a decision that the product patent in suit is invalid."

Chakrabarty's bacterium not only has a changed name, it has a new and distinctive form, quality and property. That is, the new bacterium has a plurality of plasmids coded for different oil components, and these plasmids enable the single bacterium strain to digest plural component oil. Under the *Broydex* test, like the patented fur, Chakrabarty's bacterium is a "manufacture".

B. Composition Of Matter

Deller's *Walker on Patents,* 2d edition, Baker, Voorhis & Co., Inc., 1964, a standard treatise, says this about "composition of matter":

> "The phrase 'composition of matter,' as used in the patent statutes, covers all compositions of two or more substances. It includes all composite products whether they are the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." § 18, pages 127, 128.

A much older text "The Law of Patents for Useful Inventions" by William C. Robinson, Little, Brown and Company, 1890, says:

> "A composition of matter is an instrument formed by the intermixture of two or more ingredients, and possessing properties which belong to none of these ingredients in their separate state." § 192, page 278.

In *P. E. Sharpless Co.* v. *Crawford Farms, Inc.,* 287 Fed. 655, 658 (2d Cir. 1923) appears the following:

> "A patentable composition of matter may well result or be formed by the intermixture of two or more ingredients, which develop a different or additional property or properties which the several ingredients individually do not possess in common."

Chakrabarty's bacterium contains two or more plasmids providing it with the new capability of itself degrading two or more components of oil. Thereby, the bacterium has properties which belong to none of its individual ingredients, its separate plasmids.

The CCPA held that Chakrabarty's bacterium was either a "manufacture" or "composition of matter", finding it unnecessary to distinguish between them (Pet. App. 44a). In doing so, the court called attention to the fact that the Patent Office had allowed claims to the bacterium on a carrier:

> ". . . the PTO [Patent & Trademark Office] obviously has no hesitation in issuing a patent on the living bacterium or inoculum when applied to or mixed with straw, which combination it must consider to be a manufacture or a composition of matter under § 101. . . ." (Pet. App. 35a.)

The Patent Office Board of Appeals admitted that the language of the statute does not exclude living organisms (Pet. App. 161a). Here, the Government does not contend otherwise. Chakrabarty's bacterium properly was held to be within the statutory classes.

V. CONGRESSIONAL INTENT CONCERNING LIVING MICRO-ORGANISMS WAS NOT EVIDENCED BY PASSAGE OF THE PLANT PATENT ACT (1930) OR THE PLANT VARIETY PROTECTION ACT (1970)

The Government here contends that the passage of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 by much later Congresses is evidence that patents to all living things were excluded from the terminology "manufacture" and "composition of matter" chosen by much earlier Congresses.

The most that can be said is that the Congress believed in 1930 that plants were not patentable under the prior patent law. The legislative history of the Plant Patent Act, however, does not reveal either by expression or by implication, that the living nature of plants was what placed them outside the scope of the patent law.

A brief review of the background of the Plant Patent Act is in order.

The Commissioner of Patents in 1889 held in *Ex parte Latimer,* 1889 C.D. 123, 46 O.G. 1633 that claims to a component of a pine tree were not patentable. Latimer claimed "a new article of manufacture" consisting of parts extracted from needles of particular species of pine tree. The process of extraction was

patented but claims to the product were refused. The Commissioner stated:

> ". . . the mere ascertaining of the character or quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention, recognized by the statute, any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found . . ." 1889 C.D. at 125.

The Commissioner also said:

> "that . . . patents might be obtained upon the trees of the forest and the plants of the earth . . . of course would be unreasonable and impossible." 1889 C.D. at 126.

Latimer did not convert the material of the pine needle to a patentable manufacture merely by extracting it. However, if he had taken additional steps to cause the extract to have a new quality or function, the modified extract would have been a manufacture, and thus within the statutory classes of invention.

> "If applicant's process had another final step by which the fiber thus withdrawn or separated from the leaf or needle in its natural state were changed, either by curling it or giving it some new quality or function which it does not possess in its natural condition as fiber, the invention would probably cover a product, because the natural fiber, passing through the exigencies of such a process would be treated and become something new or different from what it is in its natural state." 1889 C.D. at 127.

There is marked similarity between this reasoning and the comments of this Court in holding invalid the

borax-coated orange patent in *American Fruit Growers* v. *Brogdex Co.*, 283 U.S. 1 (1931).

Under the rationale of *Latimer*, it appears that the work of the plant breeder did not qualify for a patent because there was insufficient change in the plant caused by man. As said in one of the Government's authorities, a biography of Luther Burbank:

> "When two plants are united to produce a third, no human intelligence can predict just what will follow." *New Creations in Plant Life*, W. S. Harwood, The MacMillan Co., 1905, page 31.

The "general character" of Burbank's work was said to be in two forms:

> "1. Breeding.—This, in its basic meaning, consists in uniting two plants to give birth to a third.
>
> * * *
>
> Breeding is accomplished by sifting the pollen of one plant upon the stigma of another, this act, pollenation, resulting in fertilization, Nature, in her own mysterious ways, bringing forth the new plant.
>
> 2. Selection.—This consists in eternally choosing the best and rejecting the worst. It is co-equal in importance with breeding, the one supplementary to the other at all points." *Id.*, page 25.

Though labor, mental and physical, was certainly involved, both in breeding and selection, it apparently was concluded that insufficient change to the plant was caused by man (rather than nature) to make the new plant a manufacture. It remained a product of nature.

The Government seeks to compare Chakrabarty's work with that of the ordinary plant breeder (Br. 27, fn. 32; Br. 33-34, fn. 39-40). The great difference is apparent from Chakrabarty's own description of his work (App. 46-47). He repeatedly transferred plasmids from cell to cell and purified the results, all to obtain exactly what he set out to obtain, a strikingly new plural plasmid bacterium capable of digesting multiple oil components. As the Patent Office Board of Appeals expressly found (Pet. App. 163a) that product was made by Chakrabarty, *not* by nature. To be sure, some plant breeders did more than merely allow nature to modify; some used drugs, others used radiation. Whether the results of such work were or were not patentable is not known. But the 1930 Act was not directed at such work. The ordinary plant breeder's efforts qualified, if the result was a new and distinct variety.

In any event, it became an accepted tenet of patent law that plants were not patentable. The work of plant breeders such as Luther Burbank was, of course, extremely valuable, but lack of patent protection made it impossible to prevent copying.

To provide incentive for breeders, the Congress was petitioned to amend the patent law to allow patents on plants. By 1923 the clamour was sufficiently loud that an article on the subject was published in the primary journal of patent law, the *Journal of the Patent Office Society* (Thorne, "Relation of Patent Law to Natural Products," 6 JPOS 23 (1923)). That article expressed the view that the product of the plant breeder was outside the existing patent law because it was a natural product. Reliance was placed on *Ex parte Latimer, supra.*, and on the law of nature cases, *Morton* v. *N.Y. Eye Infirmary*, Fed. Case No. 9865,

17 Fed. Cas. 879 (C.C. S.D. N.Y. 1862) and *Wall* v. *Leck*, 66 Fed. 552 (9th Cir. 1895).[23]

The legislative history of the 1930 Plant Patent Act (Act of May 23, 1930, 46 Stat. 376) is consistent with the product of nature explanation. Commissioner of Patents Robertson referred to an earlier law of nature decision, *In re Kemper*, Case No. 7,687, 14 Fed. Cases 286 (C.C. D.C. 1841), in responding to a less limited version of the legislation than actually passed the Congress. Under that version (H.R. 9765, S.3530, 71st Cong., 2d Sess.) a mere plant finder would have been entitled to a patent for exclusive asexual reproduction of the found plant. Robertson said:

> ". . . a very serious question arises as to whether the definition given the words 'invention' and 'discovery' in the proviso in the bill, namely, that they shall be interpreted 'in the sense of finding a thing already existing and reproducing the same as well as in the sense of creating,' does not go beyond the power which the Constitution grants to Congress. Under that proviso the person who is given the right to get a patent, if the found variety is new, has done nothing whatever in any way toward creating that variety." Hearings Before the Committee on Patents, House of Representatives, 71st Cong., 2d Sess., on H. R. 11372, April 9, 1930, page 6.

[23] The Ninth Circuit in *Wall* pointed out the difference between a natural product and a manufacture:

> "The laws . . . do not permit any man to exclusively use the conditions which are the gifts of nature, simply because he was the first one to discover its value. Not until some new instrument or method is contrived for its direction towards ends which it cannot naturally accomplish does his creative genius manifest itself." 66 Fed. at 558.

Here, Chakrabarty's bacterium simultaneously degrades multiple components of oil, an end not accomplished by a mixture of naturally occurring bacteria.

Underlining his concept that a plant was not made by man, as was a manufacture under existing law, Commissioner Robertson suggested revision of the statute defining the patentees' right to exclude, saying:

> "This suggestion is made because the word 'make' in the statute is usually understood to mean the construction by human activity whereas these plants are reproduced by growth, a person only putting the graft or scion, for example, in such a position, in the tree to be grafted upon, that it will grow." *Id.*, at 7.

The Commissioner also called attention to the difficulty of a plant inventor complying with the enabling disclosure requirements of the patent law, by which an inventor's description must be sufficient to enable a reader to reproduce the invention. He suggested relaxation of the disclosure requirements as to plants.

As a direct result of the Commissioner's comments: 1) the proviso which would have permitted a patent to a plant finder was eliminated; 2) R.S. 4884 was revised to qualify asexual reproduction as an act of infringement; and 3) the suggested relaxation of the disclosure requirement was adopted. H.R. 11372 and S. 4015 were introduced to implement these suggestions. (S. 4015 contained the finder provision, as introduced. However, as reported, that provision was omitted.)

Pointedly, the Commissioner made no reference whatever to the living nature of plants, or any other living thing, as preventing patenting. Nor did the Committee Reports.

By skillful quotation out of context, the Government seeks to create a different impression. The inanimate nature of the mineral (Br. 32) was not the Committee's emphasis, but rather the natural character of the mineral. Product of nature vs. product of man was the emphasis.[24] Also emphasized was the manual act of asexual reproduction, which was required by the bill before a patent could be granted. The Committee's statement was a rebuttal to the suggestion that the work of a plant breeder was mere discovery of a product of nature:

> "There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man and is likely to be discovered in various parts of the country; and, being the property of all those on whose land it may be found, its free use by the respective owners should of course be permitted. On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man, and such discoveries can only be made available to the public by encouraging those who own the single specimen to reproduce it asexually and thus create an adequate supply.
>
> "It is obvious that nature originally creates plants but it can not be denied that man often controls and directs the natural processes and produces a desired result. In such cases the part played by nature and man can not be completely separated or weighed or credited to one or the other. Nature in such instances, unaided by man does not reproduce the new variety true to type." H.R. Rep. No. 1129, 71st Cong., 2d Sess., page 7; S. Rep. No. 315, 71st Cong., 2d Sess., page 6.

[24] Commissioner of Patents Watson, in 1954, confirmed that interpretation in commenting on a bill (now law) which would make newly found seedlings patentable under the plant law:

> ". . . the primary basis for holding the law then under consideration [Plant Patent Act] to be constitutional was that there is a 'clear and logical distinction' between the finding of a mineral which 'is created wholly by nature unassisted by man' and a 'plant discovery resulting from cultivation' which cannot 'be reproduced by nature unaided by man.'
>
> • • •
>
> "It has been consistently held in other fields that the mere discovery of an article or composition which is old in nature cannot in itself form the basis for a patent." S. Rep. No. 1937, July 19, 1954, 83rd Cong., 2d Sess., 1954 U.S. Code Cong. & Admin. News 3981, 3983-4.

Moreover, the two references in the Committee Reports to the letter from the Secretary of Agriculture (Br. 24-25) were not to the Secretary's opinion that the patent laws then covered only "inventions or discoveries in the field of inanimate nature." As apparent from the material just quoted, the Committees were aware that inanimate natural things were not patentable, even if Secretary Hyde was not. Clearly, they relied on no such opinion. What they did rely on was his approval of the proposed legislation (H.R. Rep. No. 1129, *supra,* at page 3) and his comments on use of Agriculture Department materials and personnel in determining novelty of plant varieties (H.R. Rep. No. 1129, *supra.,* at page 6). For patent law, the Committees relied on the Commissioner of Patents.

The 1930 Plant Patent Act was passed within three months of introduction of the initial bills. A single 40 minute hearing was held in the House; none in the Senate. Both chambers of the legislature were obviously receptive to the need to create patent protection for plants.

The history with respect to patents directed to single cell organisms, such as fungi, yeast and bacteria, is quite different from the history regarding plants. In direct contrast to the accepted tenet that plants were not patentable, the Patent Office was issuing patents with product claims that included single cell organisms.

The following patents were identified in the search described earlier:

Date	*Inventor*	*Patent No.*	*Claims*
1873	Pasteur	141,072	Purified Yeast
1908	Coates	899,155	Ground vegetable or animal matter inoculated with bacteria
1910	Collett	952,418	Bacteria mixed with cocoa
1914	Earp-Thomas	1,099,121	Sterilized soil inoculated with bacteria
1914	Odle	1,120,330	Food product containing lactic acid bacilli
1916	Palma	1,178,941	Bacteria combined with nitrates
1918	Harris et al.	1,260,899	Lactic acid bacteria and inert material
1923	Stoltz	1,442,239	Nitrifying bacteria combined with calcium carbonate, phosphate rock, and humus
1923	Whitmore	1,457,097	Microorganism in vegetable oil
1925	Reichel et al.	1,540,951	Lactobacillus and culture media
1930	Earp-Thomas	1,758,937	Lactobacteria and culture medium in emulsion

In each of the above patents, a claim was granted either to a live organism alone or to a live organism as one element of a composition; a live organism was a critical element in each claim. These patents demonstrate that the Patent Office did not regard the fact that an organism was alive as a disability to directing claims to it.

In 1930, plants were understood not to be patentable subject matter. The 1930 Plant Patent Act was a step taken by Congress to extend the ambit of patents into an area in which patents had previously been considered not to extend. As the opinion below properly notes, the focus of Congress was solely on plants. The Government has not demonstrated that any comparable disability applied to single cell organisms such as fungi, yeast and bacteria, and the above patents demonstrate that none existed. No comparable legislation was needed or considered in the case of fungi, yeast or bacteria.

The Government here has seized upon an action by the 1930 Congress which expanded patent protection and is attempting to use it as a basis to restrict patent protection in another area. The action of the 1930 Congress was an endorsement of the vitality of patents; it is wholly antithetical to the underlying positive concept of the 1930 Plant Patent Act to use it now, by contrived inference, in a negative fashion as a basis to exclude subject matter which previously has qualified for patent protection.

The Government's hypothesis that the 1930 Plant Act clearly established that living organisms were not patentable is further negated by the fact of continued issuance of patents to such organisms.

For example:

Date	*Inventor*	*Patent No.*	*Claims*
1932	Farr	1,851,165	Milk curd containing living *Bacillus acidophillus*
1932	Sinden	1,869,517	Cereal substrate inoculated with mushroom myceleum
1933	Torok et al.	1,894,135	Yeast combined with bacterium
1934	Reichel et al.	1,957,555	Stabilized lactobacilli concentrate
1935	Mazzucchi	1,989,014	Anthrax spore in medium containing saponin.
1936	Fowler	2,027,374	Live *Bacillus alcaligeres* in a mouth wash
1937	Loughlin	2,096,377	Inoculum containing bacterial culture
1937	Hendrickson	2,098,918	*Rhizobrium* bacteria on silica gel
1938	Nordsiek	2,121,442	Mixture of bacteria
1939	Winegarden	2,151,364	Anthrax spore in medium containing aluminum hydroxide
1940	Bond	2,200,532	Mixture of bacteria
1941	Lescarboura	2,262,851	Root pulp with mushroom mycelium
1942	Meier	2,268,955	Bacteria strain and bacterial products from cultivation on plasma

It is against this background of granting patents directed to living organisms that the 1952 Patent Act

retained the terms "manufacture" and "composition of matter." Congress could have amended the Act then, or later, to specifically exclude microorganisms or living things but it did not choose to do so.[25]

The Government also attempts to use as evidence for its thesis the Plant Varieties Protection Act of 1970. That Act is even less relevant than the 1930 Plant Patent Act. The Government agrees (Br. 27) with the interpretation by the court below that the exclusion of fungi and bacteria from this Act was merely legislative recognition of the CCPA's earlier decision in *In re Arzberger,* 112 F.2d 834, 837 (CCPA 1940) that bacteria were not plants under the 1930 Act. Moreover, the Committee Report clearly establishes that the enactment of the 1970 Act did not change the patent laws:

> "The Committee accordingly has examined S. 3070 and finds that it does not alter protection currently available within the patent system." S. Rep. No. 91-1246, 91st Cong., 2d Sess., page 3.

As the CCPA pointed out (Pet. App. 51a), this Court frequently has held:

> " '[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.' *United States* v. *Price,* 361 U.S. 304,

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[25] Specific exclusions, of course, can and have been made by the Congress, where that body deemed that patents should not be available. For instance, the Atomic Energy Act of 1946 excluded patent protection for inventions:

> ". . . useful solely in the production of fissionable material or in the utilization of fissionable material or atomic energy for a military weapon." Section 11a1, 60 Stat. 755

That exclusion was repeated in a more limited way in the Atomic Energy Act of 1954, 68 Stat. 919, 42 U.S.C. 2181.

313 (1960); *accord, United States* v. *Southwestern Cable Co.*, 392 U.S. 157, 170 (1968); *United States* v. *Philadelphia National Bank*, 374 U.S. 321, 348-49 (1963); *Rainwater* v. *United States*, 356 U.S. 590 (1958); *United States* v. *United Mine Workers*, 330 U.S. 258, 281-82 (1974)."

This is particularly true when the later Congress doesn't even express its view of what the earlier Congress intended. The 1930 Congress nowhere stated a view of the intent of earlier Congresses as to living subject matter and the 1970 Congress did not purport to change the scope of patent protection. Since the Patent Office, which has the obligation of administering the patent laws, granted patents on living things both before and after the 1930 Act, patent protection for bacteria is and has been permitted by the patent statutes.

Chakrabarty's man-made bacterium, being a manufacture or a composition of matter, is within the scope of 35 U.S.C. 101. Its living character does not foreclose patentability as consistent interpretation by the Patent Office, prior to this case, shows. If the Government wishes to reverse its policy, it should address its desires to the Congress, which can legislate an exclusion, if that is found to be required by the public interest. In the meantime there is no justification for this Court to read the limitation to nonliving subject matter into the patent law. As the court below stated (Pet. App. 70a), this Court said in *United States* v. *Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933):

> "We should not read into the patent laws limitations and conditions which the legislature has not expressed."

CONCLUSION

For the foregoing reasons, the judgment of the United States Court of Customs and Patent Appeals should be affirmed.

Respectfully submitted,

EDWARD F. MCKIE, JR.
SCHUYLER, BIRCH, MCKIE & BECKETT
1000 Connecticut Avenue
Washington, D.C. 20036
202-296-5500

LEO I. MALOSSI
General Electric Company
Corporate Research and Development
P.O. Box 8
Schenectady, New York 12301
518-385-8514

Attorneys for Respondent

Of Counsel:

WILLIAM E. SCHUYLER, JR.
DALE H. HOSCHEIT

APPENDIX

706.03(a) Nonstatutory Subject Matter

Patents are not granted for all new and useful inventions and discoveries. The subject matter of the invention or discovery must come within the boundaries set forth by 35 U.S.C. 101, which permits patents to be granted only for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.

The term "process" as defined in 35 U.S.C. 100, means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

Decisions have determined the limits of the statutory classes. Examples of subject matter not patentable under the Statute follow:

Printed Matter

For example, a mere arrangement of printed matter, though seemingly a "manufacture," is rejected as *not being within the statutory classes*. See In re Miller, 164 USPQ 46, 57 CCPA 809 (1969); Ex parte Gwinn, 112 USPQ 439 (Bd. App. 1955); and In re Jones, 153 USPQ 77, 54 CCPA 1218 (1967).

Naturally Occurring Article

Similarly, a thing occurring in nature, which is substantially unaltered, is not a "manufacture." A shrimp with the head and digestive tract removed is an example. Ex parte Grayson, 51 USPQ 413.

Method of Doing Business

Though seemingly within the category of a process or method, a method of doing business can be rejected as not being within the statutory classes. See Hotel Security Checking Co. v. Lorraine Co., 160 Fed. 467 and In re Wait, 24 USPQ 88, 22 CCPA 822 (1934).

Scientific Principle

A scientific principle, divorced from any tangible structure, can be rejected as not within the statutory classes. O'Reilly v. Morse, 15 Howard 62.

This subject matter is further limited by the Atomic Energy Act explained in § 706.03(b).

UNITED STATES PATENT OFFICE

3,420,742

Patented Jan. 7, 1969

MILK FERMENTING PRODUCT AND METHOD OF MAKING SAME

STEWART M. FARR, Kalamazoo, Mich., assignor to Dairy Technics, Inc., Kalamazoo, Mich., a corporation of Michigan

No Drawing. Continuation-in-part of application Ser. No. 285,858, June 6, 1963. This application Oct. 16, 1964, Ser. No. 404,526

U.S. Cl. 195-59 16 Claims
Int. Cl. C12k *3/00*

ABSTRACT OF THE DISCLOSURE

A method of producing a mixed bacterial concentrate which comprises separately incubating in separate culture media two or three types of bacteria, the first type being selected from the group consisting of *Streptococcus lactis, Streptococcus cremoris, Lactobacillus bulgaricus* and *Streptococcus thermophilus,* the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus,* and the third type consisting of *Streptococcus diacetylactis,* concentrating the respective media to obtain separate concentrates of the two or three type of bacteria, mixing together the two or three types of bacteria in the desired proportions to produce a mixed concentrate without permitting further growth of the bacteria, and then freezing the mixed concentrate so that it can be stored for a long time without major loss in the viability of the bacteria. A stabilized mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two or three types of bacteria, as aforesaid, the concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium and the concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

* * * * * * * * * *

What Is Claimed Is:

* * * * * * * * * *

4. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two types of bacteria, the first type being selected from the group consisting of *Streptococcus lactis, Streptococcus cremoris, Lactobacillus bulgaricus* and *Streptococcus thermophilus,* and the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus,* said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

5. A stabilized mixed bacteria concentrate according to claim 4, in which the concentrate contains at least about 10×10^9 cells per ml.

6. A stabilized mixed bacteria concentrate according to claim 4, in which the stabilizing agent is glycerol.

7. A stabilized mixed bacteria concentrate according to claim 4, in which the bacteria of said first type comprise of at least about 88% of the total count in the bacteria concentrate.

* * * * * * * * * *

10. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of three types of bacteria, the first type being selected from the group consisting of *Streptococcus lactis, Streptococcus*

cremoris, Lactobacillus bulgaricus and *Streptococcus thermophilus*, the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus* and the third type consisting of *Streptococcus diacetylactis*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

11. A stabilized mixed bacteria concentrate according to claim 10, in which the concentrate contains at least about 10×10^9 cells per ml.

12. A stabilized mixed bacteria concentrate according to claim 10, in which the stabilizing agent is glycerol.

13. A stabilized mixed bacteria concentrate according to claim 10, in which the bacteria of the second type comprise about 8% of the total count of the bacteria concentrate, the bacteria of the third type comprise between about 1% and 4% of the total count of the bacteria concentrate, the balance being bacteria of the first type.

14. A stabilized bacteria concentrate consisting essentially of a substantially neutralized concentrate of a bacteria selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, the concentrate being frozen so it can be stored for a long time without major loss in the viability of the bacteria, the concentrate containing at least about 10×10^9 cells per ml.

15. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two types of bacteria, the first type consisting of *Streptococcus lactis*, and the second type being selected from the group

consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

16. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of three types of bacteria, the first type consisting of *Streptococcus lactis*, the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, and the third type consisting of *Streptococcus diacetylactis*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

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Group 170 Paper No. 19
Appeal No. 822-58 RHI

IN THE UNITED STATES PATENT OFFICE

BEFORE THE BOARD OF APPEALS

Ex parte Stewart M. Farr

Application for Patent filed October 16, 1964, Serial No. 404,526. A Milk Fermenting Product and Method of Making Same.

Woodhams, Blanchard and Flynn for appellant.

Before Asp, Magil and Behrens, Examiners-in-Chief.
Asp, Examiner-in-Chief.

This is an appeal from the final rejection of claims 5 through 8, 11 through 14, 17, 18 and 19. Claims 1, 2, 3, 9 and 10 stand allowed.

Claim 5 is reproduced as illustrative.

5. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two types of bacteria, the first type being selected from the group consisting of Streptococcus lactis, Streptococcus cremoris, Lactobacillus bulgaricus and Streptococcus Thermophilus, and the second type being selected from the group consisting of Streptococcus citrovorus and Streptococcus paracitrovorus, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

No references have been relied upon.

Claims 5 through 8, 11 through 14, 17, 18 and 19 have been rejected as not defining an invention within the meaning of 35 U.S.C. 101. This is the sole issue in the case since

the rejection on the prior art was withdrawn. The Examiner appears to have interpreted these claims as being for mixtures of bacteria which are nothing more than the unpatentable discovery of a handiwork of nature on the authority of Funk Brothers Seed Company *v.* Kalo Inoculant Company, 333 U.S. 127; 1948 CD 671; 608 OG 641; 76 USPQ 280.

Appellant denies the applicability of this decision to the instant claims which define a composition in the frozen state containing bacteria in admixture with additional ingredients, namely, a nutrient medium and a stabilizing agent (glycerol). His invention, he says, is not "a discovery of nature" but rather the "nonobvious manipulation, utilization or application of known things to produce a utilitarian tangible composition of matter." We believe this to be the correct view of the nature of the invention. The holding of the majority in the case relied upon by the Examiner seems to have been based upon a lack of invention in the claimed mixture of strains of Rhizobium bacteria following which the decision concluded with the statement that ". . . we do not consider whether the other statutory requirements contained in 35 U.S.C. § 31, R.S. § 4886 are satisfied." In any case the claims before us are readily distinguishable from the subject matter considered in the Funk *v.* Kalo decision.

We note that the patents cited in the Examiner's action, Paper No. 4, contain claims to cultures of bacteria. Attention is also directed to *In re* Davis et al., 49 CCPA 1196; 305 F. 2d 501; 1962 CD 456; 783 OG 1244; 134 USPQ 256 which presented claims to vaccines containing both live and dead antigens of either viral or bacterial origin.

The Examiner in his answer appears to have considered the aspect of aggregation and also the "lack of invention" in the nutrient and preservative but to defeat the claims on this basis would require citation of pertinent prior art. We also note that claim 17 is for a single bacterium pre-

served in the stated form rather than for a mixture of different bacteria.

The rejection of the foregoing claims on the basis advanced by the Examiner cannot be sustained.

The decision of the Examiner is reversed.

REVERSED

BOARD OF APPEALS

/s/ N. A. Asp
Examiner-in-Chief

/s/ H. Magil
Examiner-in-Chief

/s/ Arthur H. Behrens
Examiner-in-Chief

Woodhams, Blanchard and Flynn
2026 Rambling Road
Kalamazoo, Michigan 49001

United States Patent Office

3,642,982

Patented Feb. 15, 1972

UTILIZATION OF LIVING BACTERIA AS INSECTICIDES

Rokuya Morimoto, Neyagawa, and Reijiro Kodama, Toyonaka, Japan, assignors to Takeda Chemical Industries, Ltd., Osaka, Japan

No Drawing. Continuation-in-part of application Ser. No. 341,436, Jan. 30, 1964. This application Aug. 2, 1965, Ser. No. 476,682

Claims priority, application Japan, Feb. 2, 1963, 38/5,234; Aug. 6, 1964, 39/44,997
Int. Cl. A01n *15/00*

U.S. Cl. 424—93 9 Claims

Abstract of the Disclosure

Alkalophilic and acid-producing bacteria—*Serratia piscatorum, Streptococcus faecalis, Aerobacter aerogenes*—are cultured to produce living cells which are useful insecticidally, more especially against lepidopterous larvae, such as common cabbage worm, etc.

• • • • • • • • • •

What Is Claimed Is:

1. An insecticidal composition containing living bacteria consisting essentially of an inert insecticidal carrier and *Serratia piscatorum* ATCC No. 17999 or *Streptococcus faecalis* ATCC Nos. 15335, 14336 and 19000, the living bacterium being present in an amount of 0.05 to 5 weight percent.

2. An insecticidal composition according to claim 1, wherein the carrier is the culture medium in which the bacterium was grown.

3. An insecticidal composition according to claim 1, wherein the carrier is the dried culture medium in which the bacterium was grown.

4. The composition of claim 1, wherein the living cells are cells of *Serratia piscatorum* Breed ATCC No. 17999.

5. The composition of claim 1, wherein the living cells are cells of *Streptococcus faecalis* Andrews and Horder ATCC No. 15335.

6. The composition of claim 1, wherein the living cells are cells of *Streptococcus faecalis* Andrews and Horder ATCC No. 15336.

7. The composition of claim 1, wherein the living cells are cells of *Streptococcus faecalis* Andrews and Horder ATCC No. 19000.

• • • • • • • • • •

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
DALE E. BORDT ET AL	:	
Serial No. 700,251	:	Group Art Unit 125
Filed: June 25, 1976	:	Examiner: S. Rosen

For: DIPLOID PORCINE EMBRYONIC CELL STRAINS, CULTURES PRODUCED THEREFROM, AND USE OF SAID CULTURES FOR PRODUCTION OF VACCINES

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

AMENDMENT

Responsive to the Office Action mailed May 31, 1977, please amend the above-identified application as follows:

IN THE CLAIMS

—— 3 (Twice amended). A diploid porcine embryonic cell strain characterized by:

(A) freedom from

(i) specified viral contaminants as measured by cytopathology, hemadsorption, inclusion body [straining] staining, and fluorescent antibody techniques,

(ii) specified bacterial contaminants as measured by sterility testing,

(iii) mycoplasma contamination as measured by brothagar subculturing;

(B) nontumorigenicity in immunologically depressed hamsters;

(C) possessing a substantially constant degree of viral susceptibility;

(D) capable of maintaining substantial diploidy and not becoming senescent after at least 36 subculturings, while remaining free from morphological transformation and chromosomal anomalies; and

(E) retention of marker chromosomes[.] ;

and a suitable culture medium therefor.——.

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REMARKS

The Examiner is thanked for the telephone interview courteously granted Applicants' attorney on June 13, 1977. Based upon the helpful suggestions of the Examiner Claim 3 has been amended and independent Claim 14 has been added.

• • • • • • • • • •

The Examiner is thanked for citing the Green reference "to show a type of cell claim which may be found allowable." It is believed that Applicants' amendment of Claim 3 obviates the rejection of Claims 3, 5, 9 and 11 (and newly independent Claim 14) based upon the Examiner's allegation that, prior to the present amendment, they were "directed to nonstatutory subject matter (35 USC 101)." With the Greeen reference "type of cell claim" in mind, and based upon the Examiner's suggestion during the telephone interview, Applicants have amended Claim 3 to recite that their novel diploid porcine embryonic cell strain is in "a suitable culture medium therefor." Support for his added language is found, for example, on page 2, lines 3-4; page 4, lines 7-10; page 4, line 29; page 5, line 3; page 7 *et seq.* (note particularly the examples which recite culture media) of the specification.

• • • • • • • • • •

UNITED STATES PATENT

4,166,112

Aug. 28, 1979

MOSQUITO LARVAE CONTROL USING A BACTERIAL LARVICIDE

Inventor: *Leonard J. Goldberg*, Albany, Calif.

Assignee: *The United States of America as represented by the Secretary of the Navy*, Washington, D.C.

Appl. No.: *888,083*

Filed: *Mar. 20, 1978*

Int. Cl.[2] *A01N 15/00*

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Field of Search 424/93

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Primary Examiner—Donald G. Daus
Assistant Examiner—M. C. Eakin
Attorney, Agent, or Firm—R. S. Sciascia; Charles D. B. Curry

ABSTRACT

A method of controlling mosquito larvae, by using a spore-forming bacillus ONR-60A obtained from screening clonal isolates from soil samples of known mosquito larval breeding sites. A larvicide comprising the bacillus and a carrier is formulated as a buoyant colloidal suspension which stabilizes just under the surface of the water to concentrate in the feeding zone of many varieties of mosquito larvae.

7 Claims, No Drawings

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What Is Claimed Is:

1. A bacterial larvicide active against mosquito-like larvae comprising:

(a) an effective larva killing concentration of spores of the pure biological strain of *Bacillus thuringiensis* var WHO/CCBC 1897 as an active ingredient; and

(b) a carrier.

2. A bacterial larvicide as recited in claim 1 wherein said spores and said carrier when mixed have the properties of a buoyant colloidal suspension.

3. The composition of claim 2 wherein said carrier comprises:

(a) dioxane; and

(b) a non-mineral, bio-degradable oleaginous liquid.

4. The composition of claim 3 wherein the admixture of the said spores and the said carrier forms a buoyant colloidal suspension just below the surface of the water in the feeding zone of mosquito-like larvae upon addition of water to said admixture.

5. The composition of claim 4 wherein said oleaginous liquid has specific gravity less than one.

6. The composition of claim 4 wherein said oleaginous liquid has hydrophilic properties.

7. The composition of claim 4 wherein said oleaginous liquid is jojoba oil obtained from the jojoba plant.

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"The process of producing recombinant DNA molecules and introducing them into cells is illustrated in the drawing on the opposite page.

The cell represented at the upper left contains chromosomal DNA and several separately replicating DNA molecules. The nonchromosomal DNA molecules can be isolated from the cell and manipulated to serve as vectors (carriers) for DNA from a foreign cell. Most DNA molecules used as vectors are circular. They can be cleaved, as shown, by enzymes (restriction endonucleases) to yield linear molecules with rejoinable ends.

At the upper right is another cell, represented here as a rectangle. It serves as the source of the foreign DNA to be inserted into the vector. This DNA can also be cleaved by enzymes. The rectangular cell could be derived from any living species, and the foreign DNA might contain chromosomal or nonchromosomal DNA, or both.

In the next steps, the foreign DNA fragment is mixed and combined with the vector DNA, and the recombinant DNA is reinserted into a host cell. In most experiments this host cell will be of the same species as the source of the vector. The recipient cells are then placed under conditions where they grow and multiply by division. Each new cell will contain recombinant DNA.

Recombinant DNA technology represents a method that is applicable to many areas of biological research. Essentially, it represents a new tool. Investigations supported by many NIH Institutes and programs utilize this technique, much as a new instrument is applied in studying many different things." Proposed Revised Guidelines, Recombinant DNA Research, Friday, July 28, 1978, 40 Fed. Reg. 33101, 33102.